UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
	Case No. 1:17-md-2804
This document relates to:	**Judge Dan Aaron Polster**
State of Montana v. Purdue Pharma, et al., *Case No. 1:18-op-45604*	**PLAINTIFF'S REPLY MEMORANDUM IN SUPPORT OF MOTION TO REMAND**

Purdue Pharma's opposition to the State of Montana's Motion to Remand this action to state court rests on a false premise: that the State's motion for a preliminary injunction, filed in state court, asked the court for a "'reassessment, reevaluation and revamping of'" the FDA's approval of the labeling on Purdue's opioids, and therefore was "'tantamount to asking the Court to second guess the validity of [the FDA's] decision.'" Opposition Memorandum at 1 (quoting *McKay v. City & Cty. of San Francisco*, 2016 WL 7425927, at *4 (N.D. Cal. Dec. 23, 2016)). That is not the case. Montana does not challenge the language in the package insert distributed with Purdue's drugs, and the State does not seek any injunctive relief inconsistent with the language in the FDA-approved labels.

In its motion for preliminary injunction, the State simply sought to prevent Purdue, during the pendency of this litigation, from making false representations about the safety of its opioid drugs in its promotional or educational activities and to make certain disclosures designed to correct Purdue's past misleading marketing. Motion for Preliminary Injunction at 2 (attached as Exhibit A to Opposition Memorandum, Doc. # 807-1). Such marketing communications are

not pre-approved by the FDA.[1] Moreover, none of the proposed disclosures are at odds with the FDA-approved labels. In other words, every aspect of the State's proposed injunctive relief could be applied without conflicting with any statement in the FDA-approved label; there is simply no conflict.[2] This fact distinguishes this case from those on which Purdue relies, and reaffirms the absence of any basis for the exercise of federal jurisdiction here.[3] Purdue may have suggestions for the language in certain disclosures, or may argue against requiring any

[1] Purdue seems to argue that if the disclosures requested in the injunctive relief have not been pre-approved by the FDA, then federal law prohibits them. But this is not the law. In fact, all of the marketing statements challenged in this litigation were made by Purdue without pre-approval by the FDA (e.g., the term *pseudoaddiction* never appears in an FDA-approved label). The marketing statements challenged by the State are illegal because they are deceptive and unfair, not because they lack FDA pre-approval.

[2] For example, the proposed injunction would require Purdue to: "Immediately cease promoting its opioid drugs, or opioids in general, as a first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing outside of active cancer, palliative, and end-of-life care), and in any promotional or education activity, disclose that opioids are to be tried only after other treatments have failed." This provision was based on the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (2016) at 19. The FDA-approved label for Purdue's OxyContin states: "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve OXYCONTIN for use in patients for whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain." OxyContin Labeling, at 1 (Purdue Opposition Ex. C). There is no conflict between the State's requested injunction and OxyContin's label, and the State expressly disclaims any requested relief that diverges from FDA-approved statements.

[3] FDA regulations do require such promotional labeling to be "consistent with and not contrary to" a drug's "approved labeling." 21 C.F.R. 201.100(d)(1). Whether the preliminary injunctive relief sought by Montana meets that test may be relevant to whether that relief should be granted or to various affirmative defenses Purdue may assert, but it does not involve any reassessment of a determination made by the FDA. That question, moreover, is a "fact-bound and situation-specific" inquiry that cannot constitute the sort of "substantial federal issue" that can give rise to federal subject matter jurisdiction under *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005). *See Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 700 (2006).

disclosures at all, but those arguments should be made before the state court when considering the details of the remedial order.

In fact, Montana's First Amended Complaint affirms the FDA's authority, as it claims that Purdue's deceptive marketing is contradicted by FDA findings. *See* First Amended Compl. ¶¶ 88 (alleging that the FDA has warned opioid product manufacturers that claims of improved function and quality of life were misleading); 4, 28, 46, 49-75 (alleging that Purdue minimized or failed to disclose the risk of addiction, contrary to the drugs' labels, which warn of the risk of addiction); 4, 118-120, 124 (alleging that Purdue's primary message in promotions was that OxyContin's tamper-resistant products are safe, while FDA guidance indicated that OxyContin did not prevent oral abuse, the most common form of abuse).

As explained in Montana's opening memorandum in support of remand, the State here asserts only state-law claims—Purdue does not dispute that no basis for federal jurisdiction appears on the face of the State's well-pleaded complaint. Opposition Memorandum at 9-10. Nor does this case raise a substantial federal issue sufficient to give rise to federal jurisdiction under the *Grable* exception to the well-pleaded complaint rule. Finally, because the State made clear in its original complaint that it would be seeking injunctive relief to bar Purdue from continuing to make false representations about the safety of its drugs in its marketing activities, and because Purdue did not remove this case to federal court until three months after that complaint was filed, the removal was untimely, an additional reason why the State's motion to remand should be granted.

I. This case does not present a "substantial federal issue" giving rise to federal jurisdiction under *Grable.*

As explained in the State's opening memorandum, Memorandum in Support of Remand at 8-11, in order to establish federal jurisdiction under *Grable*, the federal issue implicated in

state-law litigation must be "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013). Purdue cannot meet these requirements.

Purdue attempts to render the purported federal issue at stake more substantial-seeming by conflating the FDA approved labeling that appears on a drug's package insert, with the messages employed in the company's marketing activities. *See, e.g.,* Memorandum in Opposition at 1 (Montana "demands that the court order Purdue to supplant the warnings and labeling that the FDA has determined to be scientifically accurate and sufficient").[4] It misleadingly cites regulatory materials related to FDA's "exclusive regulatory authority to determine the precise content of prescription drug labeling" and the importance of "FDA-approved labeling", Opposition Memorandum at 4-5, to imply that the FDA exercises similar regulatory oversight over a drug company's marketing materials. But that is not the case. Although, generally speaking, the FDA approves the language in a drug's package insert, the agency does not generally review or preapprove a company's promotional materials. *See* First Amended Compl. ¶ 48 (alleging that neither marketing messages nor scripts relied on by Purdue's sales representatives were reviewed or approved by the FDA). Therefore, the FDA has made no determination regarding Purdue's marketing representations for the court to "second guess." Because Montana's motion for preliminary injunction sought only to restrict Purdue's marketing

[4] *See also, id*. (State's "requested injunctive relief amounts to a collateral attack on the validity of [FDA's] decision") (internal quotation omitted); *id*. at 2 ("demanding injunctive relief that would displace the federally mandated regulatory and labeling scheme for prescription medications"); *id*. at 3 ("injunctive relief [Montana] seeks directly implicates the FDA's decisions to approve Purdue's opioid medications as safe and effective"); *id*. at 4 ("substantial federal question of whether the State may use Montana law to compel Purdue to supplant the warnings and labeling that the FDA has determined to be appropriate").

representations, it in no way challenged the FDA's regulatory authority over a drug's "approved labeling" or disputed the substance of FDA's labeling determinations.[5]

The cases on which Purdue relies for its jurisdictional argument are distinguishable on precisely this basis. In *McKay*, the court correctly recognized that the plaintiffs' attempt to enjoin the use of flight paths that had been approved by the FAA was tantamount to a direct challenge to the agency's exclusive authority over flight paths. 2016 WL 7425927, at *4. Similarly, in *Bader Farms, Inc. v. Monsanto, Co.*, 2017 WL 633815 (E.D. Mo. Feb. 16, 2017), even though the plaintiffs denied that they were challenging the Animal and Plant Health Inspection Service's approval of Monsanto's marketing of genetically modified seeds, the Court recognized that they could only succeed on their fraudulent concealment count "if they establish that the agency decision was incorrect due to defendant's fraudulent concealment." *Id*. at *3. Montana, by contrast, does not challenge any decision made by the FDA regarding Purdue's approved labeling; the State's requested preliminary injunction would not affect Purdue's FDA-approved label; and the State can prevail on all of its claims without invalidating any agency action.

Once this Court recognizes that the State's suit does not directly challenge any prior FDA labeling determination, the jurisdictional inquiry becomes quite straightforward, as laid out in Montana's opening memorandum. No federal issue is "necessarily raised" by the State's preliminary injunction motion. As in all of the lawsuits filed by attorneys general against Purdue

[5] Of course, even if Montana's suit did include a claim that the labeling on Purdue's opioid drugs was inadequate under state law, that claim would not give rise to federal jurisdiction, even if the State claimed that the labeling was also inadequate under federal law. *Merrell Dow Pharma. Inc. v. Thompson,* 478 U.S. 804 (1986). States have independent authority to regulate drug labeling through their tort laws to protect the health and safety of their citizens: "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth v. Levine*, 555 U.S. 555, 575 (2009). "[S]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 578.

across the nation, the State seeks to enjoin Purdue from making misrepresentations in violation of *state* law in its marketing. Further, federal law will not be implicated by the Court's consideration of the State's preliminary injunction motion *unless* Purdue chooses to defend by asserting that the proposed terms of the injunction are inconsistent with its FDA-approved labeling. However, a federal question raised only in an affirmative defense is not "necessarily raised" and does not provide a basis for federal jurisdiction. *Caterpillar, Inc. v. Williams,* 482 U.S. 386, 392-93 (1987); *see also Alexander v Jefferson*, No. 1:11 CV 2807, 2012 WL 70330, at *2 (N.D. Ohio Jan. 4, 2012) (Polster, J.) ("[A] case may not be removed to federal court when the basis for removal is a federal defense . . . or a federal counterclaim.") (internal citation omitted).

Nor is the federal issue "substantial" as that term is used in *Grable*. As the Supreme Court already held in *Merrell Dow*, Congress has made the determination that "the presence of a claimed violation of the [FDCA]" in state-law litigation "is insufficiently 'substantial' to confer federal-question jurisdiction." 478 U.S. at 814. More generally, *Grable* jurisdiction is reserved for almost pure questions of law, such as the interpretation of the IRS notice requirement at issue in that case. By contrast, "[n]o substantial federal issue will be found where a claim is 'fact-bound and situation-specific.'" *McKay v. City & Cnty. of San Francisco*, Nos. 16-cv-03561 NC, 16-cv-03564 NC, 2016 WL 7425927, at *4 (N.D. Cal. Dec. 23, 2016) (quoting *Empire HealthChoice*, 547 U.S. at 700). Purdue asks the Court to compare the specific representations the State seeks to enjoin in its marketing with the language approved by the FDA for the drugs' labeling in search of inconsistency. This is precisely the kind of "fact-bound and situation-specific" inquiry that is considered insubstantial for jurisdictional purposes. It will affect only the

outcome of this case; it has no bearing on the respective regulatory authority of state and federal governments, contrary to Purdue's assertions.

If this Court were to compare the specific representations in the State's proposed injunctive relief with the FDA-approved labeling for all of Purdue's opioid products, the Court would find that there are no conflicts. None of the statements sought to be enjoined are in the FDA-approved labels, and none of the requested disclosures are in fundamental conflict with any of the language in those labels. *See supra*, n.2. The injunctive relief requested by the State is affirmatively supported by findings of the federal government, including the FDA.

For purposes of jurisdictional analysis, this case is quite similar to the class action against Purdue that the Southern District of Ohio remanded in *Little v. Purdue Pharma, L.P.*, 227 F. Supp. 2d 838 (S.D. Ohio 2002). Purdue attempts to distinguish *Little* as involving only "personal injury claims." Opposition Memorandum at 11. In fact, plaintiffs there, like the State here, sought to compel Purdue to correct misleading marketing information about its drug, OxyContin. Among the specific items of equitable relief sought by the plaintiffs was "an order requiring Defendants to fund and institute a general awareness campaign addressing the dangers of OxyContin." 227 F. Supp. 2d at 844, n. 5. Yet Chief Judge Rice had no difficulty finding an absence of federal jurisdiction and remanding the case to state court. The same outcome is appropriate here.

II. Purdue's Notice of Removal was Untimely.

Purdue's removal notice was untimely. A notice of removal must be filed within 30 days after the defendant's receipt of a copy of the initial pleading. 28 U.S.C. § 1446(b). Yet Purdue did not file its notice of removal until February 28, 2018—90 days after the State had filed its original Complaint.

Purdue attempts to justify its untimely filing by reference to 28 U.S.C. § 1446(b)(3), an exception to the general rule that permits removal "within 30 days after receipt . . . of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable." Purdue contends that the State's Motion for Preliminary Injunction "revealed, for the first time, the substantial federal questions raised in the State's lawsuit." Opposition Mem. at 14.[6]

The problem for Purdue, however, is that the State's original Complaint fully foreshadowed the injunctive relief the State would seek in that motion. The Complaint lays out in detail the precise unlawful acts and practices that the State alleged violated Montana law and for which injunctive relief was sought. Compl. ¶ 189 (seeking injunctive relief to halt Purdue's unfair and deceptive acts and practices, including its deceptive marketing of its opioids); Compl. ¶ 195 (seeking injunctive relief to abate the public nuisance caused by Purdue's conduct). Purdue argues that two aspects of the State's requested injunctive relief, in particular, run afoul of FDA authority: disclosure that opioids are not an appropriate first-line treatment for chronic pain and that there is no evidence that opioids improve pain, function, and quality of life long term. Purdue Mem., at 5-6. However, the State's Complaint clearly asserts that these statements are deceptive. Paragraph 152 of the Complaint alleges that Purdue encouraged the use of opioid medications as a first-line treatment option for chronic pain, and paragraph 151(h) of the Complaint alleges that Purdue deceptively claimed that chronic opioid therapy would improve patients' function and quality of life.

[6] This is not Purdue's first untimely removal of a state attorney general action. On June 13, 2018, nearly a year after the filing of the State of Oklahoma's complaint against it on June 30, 2017, and on the eve of depositions, Purdue removed that case, claiming that a discovery response first revealed a federal issue. *See* Purdue's Notice of Removal in *State of Oklahoma v. Purdue Pharma L.P.*, No. 18-574 (W.D. Okla.) (Ex. A).

Thus, while the precise terms of the requested injunctive relief may not have been specified in the Complaint, Purdue was fully on notice that Montana was invoking state court authority to enjoin its deceptive marketing representations, including those that Purdue now contends give rise to federal subject matter jurisdiction under *Grable*. Because this issue—and purported basis for federal jurisdiction—was clear on the face of the original Complaint filed three months prior to Purdue's notice of removal, the removal was untimely. For this reason as well, the case must be remanded to state court.

III. Purdue's Untimely and Improper Removal Upsets the Federal-State Balance by Subjecting Well-Pleaded State-Law Claims to Federal MDL Proceedings.

Finally, removal of this and similar cases would undoubtedly "disrupt[] the federal-state balance approved by Congress." Every state-law case involving a drug company's marketing conduct is likely to raise issues about the relationship between the requirements of state and federal law. As the Montana District Court concluded in *McGrath ex rel. Montana v. Janssen L.P.*, 2009 WL 9136812, "[w]ere the courts to take the view that a substantial federal question is necessarily raised by state tort cases filed against pharmaceutical companies, there would be a real potential for a large volume of cases to shift from state courts to federal courts." *Id.*, at *4. The untimely, improper removal to federal court of the State of Montana's well-pleaded state law claims disrupts federalism and the comity and respect the federal and state courts enjoy and owe to one another.

/ / / / /

CONCLUSION

For the foregoing reasons, the State of Montana's Motion to Remand should be granted.

Respectfully submitted, this 3rd day of August, 2018.

THE STATE OF MONTANA

___/s/ Linda Singer_____

LINDA SINGER
JEFFREY NELSON
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com
jnelson@motleyrice.com

TIMOTHY C. FOX
Montana Attorney General
DALE SCHOWENGERDT
Solicitor General
MATTHEW T. COCHENOUR
Assistant Attorney General
P.O. Box 201401
Helena, MT
Telephone: (406) 444-2026
Fax: (406) 444-3549
DaleS@mt.gov
MCochenour2@mt.gov

MARK W. MATTIOLI
Bureau Chief
KELLEY L. HUBBARD
Assistant Attorney General
Office of Consumer Protection
P.O. Box 200151
Helena, MT 59620-0151
Telephone: (406) 444-2026

Fax: (406) 442-1894
mmattioli@mt.gov
KHubbard@mt.gov

WILLIAM A. ROSSBACH
Rossbach Law, PC
P.O. Box 8988
Missoula, MT 59807
Telephone: (406) 543-5156
Fax: (406) 728-8878
bill@rossbachlaw.com

I certify that this case has not been assigned to a particular tort track and that Plaintiff's Reply in Support of Motion to Remand adheres to the page limitations specified in Local Rule 7.1(f).

/s/

Jeffrey C. Nelson

Plaintiff's Counsel

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 3rd day of August 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

___/s/_____

Jeffrey C. Nelson

Plaintiff's Counsel